

## **REMARKS**

Claim 1 has been amended by incorporating the subject matter of dependent claim 5 therein, dependent claim 5 has been canceled, and new claim 19 has been added to the application. New claim 19 is the same as original claim 1 with the subject matter of dependent claim 2 incorporated therein. In view of these amendments and the following remarks, a reconsideration and allowance of the application is requested.

## **The Invention**

The present invention is based on the discovery that implants in a subject can be more precisely located using MR imaging by acquiring two image data sets using two different types of pulse sequences (a spin-echo and a gradient-recalled echo) and producing a phase difference image from them. Such a phase difference image has little clinical value by itself, but when the implant location information therein is combined with a conventional magnitude image produced from one of the data sets, the precise location of an implant can be seen in the anatomical structures of the subject. This is particularly important where the implant is a brachytherapy seed in the prostate because it is a very small implant and its precise location is very critical to the medical procedure.

## **The Prior Art**

The Bernstein '418 patent teaches a method for producing an angiogram using an MRI system. This field is referred to as MR angiography or MRA. The object of MRA is to visualize the vasculature of the subject and null from the image all other structures. MRA does this by acquiring two data sets and effectively subtracting the two resulting images to null out static structures. Such static structures include tissues (other than moving blood) and stationary implants. In other words, one would not see a stationary implant in the MRA image produced according to Bernstein '418.

The MRA method in Bernstein '418 is a variant of the so-called phase contrast (PCMRA) method. This is an alternative to the contrast enhanced method (CEMRA). In Bernstein the two image data sets are acquired with the exact same pulse sequence except a velocity encoding gradient used in both sequences (see Figs. 3B and 3C) is flipped in polarity in one of them. The two pulse sequences must be the same because you want the stationary

tissues and structures to appear the same in both images so they null out when the difference is calculated (complex difference in this variation of the PCMRA method).

The Zhang et al '088 patent discloses a method for imaging devices in a patient with MRI. It recognizes many of the problems with imaging such devices and proposes a specific pulse sequence for use in doing this. More specifically, Zhang et al teach that a normal spin echo pulse sequence (see Fig. 2) should be modified by delaying the NMR signal acquisition by an amount  $\Delta TE$  as shown in Fig. 3. A normal image reconstruction is done and the process is repeated with a different  $\Delta TE$ .

The Sliwa et al and Slater et al patents disclose implants. They do not teach anything regarding the imaging of such implants with MRI.

#### **The Claims Are Patentably Distinguishable Over The Prior Art**

Claim 1 has been amended to clearly distinguish over Bernstein '418. Claim 1 now calls for employing the phase difference image to locate an implant in the subject. As explained above, Bernstein is an MRA method and implants are not even seen in such images. In addition, as shown best in Fig. 4 of Bernstein, the phase difference data 325 is used to calculate phase correction data 326, which in turn is used to correct a complex difference data set 330. There is no recognition anywhere in Bernstein that the phase difference data 325 can be used to locate implants. Claim 1 is, therefore, believed to patentably distinguish over this prior art reference.

Independent claims 1, 8 and 15 are non-obvious in view of either Bernstein '418, or Zhang et al '088, or the combination of the two. The claims clearly distinguish over Bernstein '418 for the reasons stated above for claim 1. The Zhang et al '088 patent does deal with the problem of imaging inanimate objects in a subject, but its solution is totally different to that disclosed and claimed by Applicant. Not only would not one skilled in the art think to combine Zhang et al with Bernstein, but they could not combine them. The whole objective of Bernstein is to null signals from everything other than moving blood. Implants or devices such as those mentioned in Zhang et al would not be seen in the Bernstein MRA method. This would be true if you used the pulse sequence disclosed in Zhang et al or any other pulse sequence in the Bernstein method. There is no recognition in either of these references that a phase difference image from two data sets acquired with two different pulse sequences can be used to locate implants, and without that recognition one

Kiaran McGee, et al.  
Serial No.: 10/016,527  
AMENDMENT  
Page 8

skilled in this art could not begin to reconstruct the claimed invention from these references. And, of course, one skilled in the art would not consider combining an MRA method with a method for imagine stationary inanimate objects.

New claim 19 is patentably distinguishable from the prior art. It is the same as original claim 1, but the pulse sequences recited in steps a) and b) are specifically identified as a spin echo and a gradient-recalled echo pulse sequence respectively. As discussed above, the Bernstein '418 patent discloses the use of the same pulse sequence in the acquisition of two data sets, but the velocity encoding gradient is flipped in polarity. To null static tissue in PCMRA, it is required that the same pulse sequence be used in both acquisitions except for the velocity encoding gradient. One skilled in the art would not, therefore, modify Bernstein to use a spin-echo in one acquisition and a gradient-recalled echo in the other acquisition as called for in claim 19 because static tissue would not null to provide an angiogram. Without a recognition that using these two different pulse sequences would provide an advantage or benefit (e.g., locate implants) one skilled in the art would not do it.


Favorable reconsideration and allowance of this application is respectfully requested.

The Commissioner is authorized to charge any fees under 37 CFR § 1.17 that may be due on this application to Deposit Account 17-0055. The Commissioner is also authorized to treat this amendment and any future reply in this matter requiring a petition for an extension of time as incorporating a petition for extension of time for the appropriate length of time as provided by 37 CFR § 136(a)(3).

Respectfully submitted,

KIARAN MCGEE, ET AL.

Date: July 1, 2003

  
Barry E. Sammons  
Quarles & Brady, LLP  
Reg. No. 25,608  
Attorney for Applicant  
411 East Wisconsin Avenue  
Milwaukee WI 53202  
414/277-5000